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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,555	07/30/2003	Kohei Miyazono	NY-LUD 5298.5-DIV-US	7477

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FULBRIGHT & JAWORSKI, LLP
666 FIFTH AVE
NEW YORK, NY 10103-3198

EXAMINER	
HISSONG, BRUCE D	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 04/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,555	MIYAZONO ET AL.	
	Examiner	Art Unit	
	Bruce D. Hissong, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-31* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

A. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 6-7, 10-19, and 30-31, drawn to an isolated protein with activin receptor type I functionality, classified in class 530, subclass 350.

II. Claims 1-5, 8-9, 10-19, and 30-31, drawn to an isolated protein with TGF-β-type I receptor functionality, classified in class 514, subclass 2.

III. Claims 20 and 30-31, drawn to an antibody that binds the protein of claims 1-19, wherein said protein has activin receptor type I functionality, classified in class 424, subclass 130.1.

IV. Claims 20 and 30-31, drawn to an antibody that binds the protein of claims 1-19, wherein said protein has TGF-β-type I receptor functionality, classified in class 424, subclass 130.1.

V. Claims 21-29 and 30-31, drawn to nucleic acids and host cells, wherein said nucleic acid encodes a protein of group I, classified in class 435, subclass 69.1.

VI. Claims 21-29 and 30-31, drawn to nucleic acids and host cells, wherein said nucleic acid encodes a protein of group II, classified in class 435, subclass 69.1.

B. The inventions are distinct, each from the other because of the following reasons:

Inventions I-VI are independent and distinct, each from each other, because they are products which possess characteristic differences in structure and function and each has an independent utility that is distinct for each invention which cannot be exchanged.

The polypeptides of groups I and II represent molecules which have distinct amino acid sequences and tertiary structure, and also possess independent utilities, and thus represent separate and distinct inventions.

The polypeptides of groups I-II and the polynucleotides of groups V-VI are patentably distinct for the following reasons: polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polypeptide and polynucleotide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. Furthermore, searching the inventions of groups I-II and V-VI together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides is not coextensive. The inventions of groups I-II and V-VI have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is also search burden in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides that would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide, but spoke to the gene. Searching, therefore, is not coextensive. As such, it would be burdensome to search the inventions of groups I-II and V-VI.

The polypeptides of groups I-II and the antibodies of group III-IV are patentably distinct for the following reasons: while the inventions of groups I-IV are polypeptides, in this instance, the polypeptides of group I-II are single chain molecules that function as a receptor, whereas the polypeptides of group III-IV encompass antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 complementary determining regions (CDRs) that function to bind an epitope. Thus, the polypeptides of groups I-II and the antibodies of group III-IV are structurally distinct molecules; any relationship between a polypeptide of groups I-II and an antibody of groups III-IV is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with a polypeptide.

In this case, the polypeptides of groups I-II are large molecules that contain potentially hundreds of regions to which an antibody must bind, whereas the antibody of group III is defined

in terms of its binding specificity to a small structure within a polypeptide of groups I-II. Thus, immunization with a polypeptide of groups I-II would result in the production of antibodies outside the scope of groups III-IV. Therefore, the polypeptide and antibody are patentably distinct.

Furthermore, searching the inventions of groups I-II and groups III-IV would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and antibody to the polypeptide require different searches. An amino acid search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of groups III-IV. Furthermore, antibodies that bind to an epitope of a polypeptide of groups I-II may be known even if a polypeptide of groups I-II is novel. In addition, the technical literature search for a polypeptide of groups I-II and an antibody of groups III-IV is not coextensive, e.g. antibodies may be characterized in the technical literature prior to discovery of, or sequencing of, their binding target.

The polynucleotide of group V-VI and the antibodies of groups III-IV are patentably distinct for the following reasons: the antibodies of groups III-IV includes, for example, IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, including framework regions which act as a scaffold for the 6 complementary determining regions (CDRs). Polypeptides, such as the antibodies of groups III-IV are composed of amino acids; polynucleotides, which are composed of nucleic acids, are structurally distinct molecules. Any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of groups V-VI will not encode an antibody of groups III-IV, and an antibody of groups III-IV cannot be encoded by a polynucleotide of groups V-VI. Therefore, the antibody and polynucleotide are patentably distinct.

The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of groups III-IV and V-VI would impose a serious search burden since a search of a polynucleotide of groups V-VI would not be used to determine the patentability of an antibody of groups III-IV and vice-versa.

The polypeptides of groups I and II are distinct because as activin and TGF-β receptors, respectively, they represent different molecules with distinct structures, functions, and utilities.

Similarly, the polynucleotides of groups V and VI are distinct because they encode separate and distinct polypeptides of groups I and II, respectively, and thus have distinct sequences and utilities. Finally, the antibodies of groups III and IV are distinct because they have different binding specificities, and thus have distinct structure and function.

C. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

D. Additionally, groups I, II, and IV, are subject to further restriction. It is noted that the claims are drawn to examination of at least one of a number of structurally distinct and non-overlapping polypeptides. In order to be fully responsive, applicant is required to further elect one specific protein if electing group I or II, or nucleic acid if electing group IV, selected from SEQ ID NOs 2, 4, 6, 8, 10, 12, 14, 16, or 18. This is NOT an election of species. The claimed polypeptides are structurally distinct chemical compounds, and are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such polypeptide is presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141. By statute "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant.....to elect that invention to which his claim shall be restricted." 37 CRF 1.142(a). See also 37 CFR 1.141(a). It is noted that search more than one of the claimed patentably distinct peptides represents a serious burden for the office.

E. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i). Applicant is also advised that the reply to this requirement, to be complete, must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

F. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571) 272-3324. The examiner can normally be reached M-F from 8:30am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, Ph.D., can be reached at (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BDH
Art Unit 1646

ROBERT S. LANDSMAN, PH.D
PRIMARY EXAMINER